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Date 24-08-2005

Reference IMG/43565EP1	Application No./Patent No. 01968890.2 - 2310 / 1317227
Applicant/Proprietor C.R. BARD, INC.	

#### Communication of a notice of opposition

Enclosed herewith is a copy of a notice of opposition to the European patent specified above.

An invitation to file observations and to file amendments, where appropriate, to the description, claims and drawings (Rule 57(1) EPC) will be issued separately.

The period within which such observations may be filed will not be fixed until the following conditions are met:

- (a) the opposition period has expired;
- (b) the notice of opposition has been examined for certain formal requirements (Rule 56 EPC).

Enclosure: Notice of opposition OP01 (Ethinon, Inc.) - TELEFAX -  
and cited documents

Opposition Division



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18. Aug. 2005

YOUR REF

OUR REF 0004005EP:AJF/swi

BY FAX

16th August 2005

## CONFIRMATION COPY

Dear Sirs,

**Re: European Patent No. 1317227 (Application No. 01968890.2)**  
**"Implantable prosthesis"**  
**C. R. Bard, Inc.**

European Patent No. 1317227 is hereby opposed by Ethicon, Inc., U.S. Route 22, Somerville, New Jersey 08876, United States of America. Please debit deposit account No. 2805.0059 in respect of the opposition fee.

The patent is opposed under Article 100(a), on the ground that its subject-matter is not patentable within the terms of Articles 52-57 EPC, and more particularly Articles 54 and 56. Revocation of the patent in its entirety is requested. Oral proceedings are also requested.

### Claim 1 – Interpretation

Claim 1 is in the following terms:

"An implantable prosthesis (20) for repairing a tissue or muscle wall defect, the implantable prosthesis comprising:

a layer of repair fabric (22) that is susceptible to the formation of adhesions with tissue and organs, the layer of repair fabric including a first surface (30) and an outer peripheral edge (28); a barrier layer (24) that inhibits the formation of adhesions with tissue and organs, the barrier layer being configured to inhibit the formation of adhesions between at least a portion of the first surface and adjacent tissue and organs;

and characterised by

a peripheral barrier (26) that inhibits the formation of adhesions with tissue and organs, the peripheral barrier extending about at least a portion of the outer peripheral edge of the layer of repair fabric to inhibit the formation of adhesions

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between the portion of the outer peripheral edge of the layer of repair fabric and adjacent tissue and organs." [underlining added]

The word "edge" has a number of possible meanings. It is apparently used in this claim to refer to the actual surface, albeit a very narrow one, which extends between the major faces of the repair fabric (rather than more figuratively to the marginal portion of the repair fabric). The same usage is adopted herein.

Notwithstanding this use of the word "edge", the reference to the peripheral barrier "extending about at least a portion of the outer peripheral edge of the layer of repair fabric" introduces an ambiguity into the scope of the claim:

One possible meaning is that the peripheral barrier "extends" in a generally circumferential sense, i.e. along one or more margins of the repair fabric. On this interpretation, the peripheral barrier might be said to "extend about" the outer peripheral edge of the layer of repair fabric, without necessarily being wrapped over the edge of the repair fabric. This interpretation will be referred to as interpretation "A" below.

An alternative meaning is that the peripheral barrier "extends" generally outwardly, and that "extending about" the outer peripheral edge implies that the barrier wraps at least partially around the edge of the layer of repair fabric. This interpretation will be referred to herein as interpretation "B".

It is believed that interpretation "B" is the correct one, but the following discussion of novelty and inventive step considers both interpretations.

### **Novelty - claim 1**

On interpretation "A", claim 1 of the opposed patent lacks novelty in view of WO99/06079 (D1).

D1 discloses an implantable prosthesis for repairing a tissue or muscle wall defect (see, for example, page 1, lines 8-11). The prosthesis disclosed in D1 comprises a layer of repair fabric (Figure 1, reference numeral 2; and page 9, lines 12-13). The repair fabric is susceptible to the formation of adhesions with tissue and organs (see, for example, page 5, lines 16-21).

The layer of fabric (2) in D1 self-evidently has a first surface and an outer peripheral edge.

The prosthesis of D1 also has a barrier layer (Figure 1, reference numeral 3; and page 9, lines 14-15). The barrier layer of D1 inhibits the formation of adhesions between at least a portion of the adjacent surface of the fabric and adjacent tissue and organs (see page 3, line 32 to page 4, line 3; page 4, lines 26-32; and page 5, lines 11-15).

D1 makes the following statement at page 8, lines 7-12;

"The absorbable film is preferably continuous, smooth and non-porous, entirely covering the prosthetic fabric, and more preferably projects beyond the latter in such a way as to protect the prosthesis from visceral contacts, the

overshoot being from 5 to 10 millimetres for example." [Translation taken from US-B-6264702, column 4, lines 26 to 30]

The projecting portion of the absorbable film is manifestly not meant to protect the upper surface of the fabric (as seen in Figure 1 of D1) from contact with visceral tissue, because the whole point of the prosthesis disclosed in D1 is that the upper surface of the fabric allows ingrowth of tissue. Equally clearly, the projecting portion of the absorbable film does not protect the opposite face of the fabric from visceral contacts, because that face of the fabric is already protected by the film. Plainly, therefore, the projecting portion of the absorbable film is intended to protect the edge of the fabric from visceral contacts.

The projecting portion of the absorbable film therefore constitutes a peripheral barrier which serves to inhibit the formation of adhesions between the portion of the outer peripheral edge of the layer of repair fabric and adjacent tissue and organs.

On interpretation "A", claim 1 of the opposed patent also lacks novelty in view of a product called Parietex® Composite. Parietex® Composite is sold by Sofradim Production, the Applicant in document D1, and it is made in accordance with the teachings of D1. Evidence that Parietex® Composite was available to the public before the priority date of the opposed patent is provided by a publication of Groupe Floréane, the parent company of Sofradim Production. Extracts from this publication are filed herewith as D2. The complete publication is available at [http://www.actusnews.fr/documents/ACTUS-0-664-041118\\_doc\\_de\\_ref\\_2002\\_2003.pdf](http://www.actusnews.fr/documents/ACTUS-0-664-041118_doc_de_ref_2002_2003.pdf). Page 7 of D2 states that Parietex® Composite was launched in 1999.

Evidence as to the structure of Parietex® Composite is provided by Jarsaillon P., Hernia (2000) 4 [Suppl.]: S17-S21, a copy of which is filed herewith as D3. A description of Parietex® Composite is found on page S18, right-hand column, first paragraph:

"The textile base of the composite implant (Parietex® Composite, Sofradim, France) is made up of a three dimensional multifiber polyester mesh with a hexagonal motif. This mesh has been extensively used in the past decade as a reinforcement material in hernia repair [Benchetrit 1998]. A continuous, smooth, hydrophilic and absorbable film is grafted to the surface of the textile base. This film completely covers one of the sides of the reinforcement and protects the viscera from direct contact with the textile during its tissue integration [Mutter 1998]. Once hydrated, this film is elastic and follows the deformations imposed on the mesh without separating from it. It is transparent and juts out 5 mm over the edges of the reinforcement in order to protect the edge and to facilitate the pinpointing of the sides." [emphasis added]

Parietex® Composite is self-evidently an implantable prosthesis for repairing a tissue or muscle wall defect, and it is clear from the above-quoted passage (and particularly the reference to "tissue integration") that it comprises a layer of repair fabric which is susceptible to the formation of adhesions with tissue and organs. It is also clear that the collagen film serves as barrier layer which inhibits the formation of adhesions between at least a portion of the adjacent surface of the fabric and adjacent tissue and organs.

Finally, the above quoted passage states explicitly that the portion of the collagen film which juts out over the edges of the fabric reinforcement (and which is clearly visible in Figure 4 of D3) serves to protect the edges of the fabric. It therefore constitutes a peripheral barrier which serves to inhibit the formation of adhesions between the portion of the outer peripheral edge of the layer of repair fabric and adjacent tissue and organs..

### **Novelty - dependent claims**

The fabric (2) disclosed in D1 and used in Parietex® Composite clearly includes a plurality of interstices that are constructed and arranged to allow tissue ingrowth thereto. Claim 2 of the opposed patent therefore also lacks novelty in view of D1 and Parietex® Composite.

The absorbable film of D1 and Parietex® Composite provides both the barrier layer and the peripheral barrier, and claim 8 therefore also lacks novelty in view of D1 and Parietex® Composite.

In Figure 1 of D1, and in Parietex® Composite, the peripheral barrier extends along the entire outer perimeter of the fabric layer, and claim 14 of the opposed patent therefore also lacks novelty in view of D1 and Parietex® Composite.

The absorbable film of D1 and Parietex® Composite covers an entire surface of the fabric, and claim 29 therefore also lacks novelty in view of D1 and Parietex® Composite.

### **Inventive step**

On interpretation "B", the subject-matter of claim 1 lacks inventive step in view of D1 and Parietex® Composite. The disclosure on page 8, lines 7-12, of D1 clearly teaches the desirability of providing a barrier to prevent contact of visceral tissue with the edge of the fabric. The portion of collagen film which projects beyond the edges of the fabric of Parietex® Composite is clearly intended to serve the same purpose.

The skilled person at the priority date was therefore aware of the use of a peripheral portion of absorbable film to prevent adhesions to the edge of a fabric reinforcement. No inventive step was involved in at least partially wrapping the peripheral portion of the absorbable film around the edge of the fabric, and securing it by any suitable means such as adhesive.

Claims 2, 8, 14 and 29 of the opposed patent similarly lack inventive step in view of D1, for the reasons given above in relation to lack of novelty.

On either interpretation of claim 1, the remaining claims of the opposed patent merely define design features which would have been immediately obvious to a person skilled in the art at the priority date.

Yours faithfully,

  
FISHER, ADRIAN JOHN